

CHAPTER 4

Using Reporting Guidelines Effectively to Ensure Good Reporting of Health Research

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“It is the responsibility of everyone involved to ensure that the published record is an unbiased, accurate representation of research.” [1]

Inadequate reporting of research is a major concern for several reasons (Chapter 1). If authors do not provide sufficient details about the conduct and findings of their study, readers are unable to judge the reliability of the results and interpret them. There are also ethical and moral reasons for reporting research adequately. Widespread deficiencies in research publications have been extensively documented. In recent years, they have led to the development of reporting guidelines, which outline the key elements of research that should be addressed in a research report and how [2].

The primary role of reporting guidelines is to help researchers write up their research to maximize the value to others. Adherence to reporting guidelines will increase the completeness and transparency of health research publications, thereby providing readers with sufficient details to enable them to critically appraise the study [3]. Improved reporting also has important benefits for systematic reviewers and those developing clinical practice guidelines and improves the efficiency of electronic literature searches. Over time, the use of reporting guidelines may have a beneficial influence on the quality of research by raising general awareness of key methodological issues.

In this chapter, we consider how reporting guidelines can be used by researchers and others to improve the quality of the accumulating research literature and ultimately benefit patients. We also consider whose responsibility it is to ensure good reporting of research.

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Reporting guidelines

A reporting guideline lists the minimum set of items (usually as a checklist) that should be included in a research report to provide a clear and transparent account of what was done and what was found. The EQUATOR Network's online Library for Health Research Reporting (Chapter 6) currently lists over 200 reporting guidelines. Some of these are generic for specific types of study designs (e.g., randomized trials, systematic reviews, observational studies) and should always be observed when reporting this type of study. Their primary focus is on the description of the study methods and corresponding advice on reporting the study findings. The content of each of these guidelines has been carefully considered by multidisciplinary groups of relevant experts and stakeholders, and there is a strong rationale for each item of requested information. Items range from "simple" requests such as the identification of study design in the title or abstract (necessary for the electronic identification of studies) to items focusing on specific aspects that might introduce bias into the research (e.g., details about how participants were selected for inclusion into a study). This book provides an overview of the key methodology guidelines (Chapters 7–24). However, most of the guidelines listed on the EQUATOR website are more specific, providing guidance relevant to a particular medical specialty (e.g., reporting controlled trials in oncology) or to a particular aspect of research (e.g., reporting of adverse events or particular analyses). Such specific guidelines should, ideally, be used in conjunction with the relevant generic guidelines.

Reporting guidelines do not prescribe how research studies should be conducted. Nevertheless, wider appreciation of what needs to be reported can be expected to feed into improving how future studies are designed and conducted [4]. It is not possible to separate research reporting from research conduct completely, but it is important to be aware of some specific issues arising from the close relationship between these two aspects of the research process (see Chapter 5).

Who benefits from the use of reporting guidelines?

Researchers are the primary target group of most reporting guidelines as they benefit directly from their use both as authors and peer reviewers of research articles. However, many others can indirectly benefit from the use of reporting guidelines: readers of research articles, systematic reviewers, clinical guideline developers, research funders, journal editors and publishers, patients, and society at large. All these groups benefit, in various ways, from more completely and accurately reported health research studies.

Research articles are primarily intended to communicate findings to interested parties. Other researchers are one of the most important groups who will read a published article. They may well be working in the same field and likely to be carrying out similar or related research or conducting a review of published articles.

Whether a study's findings support or refute previous research, or the study breaks new ground, fellow researchers who read the article should not simply accept the authors' findings or (especially) their conclusions. Rather, they will wish to understand the methods used, to determine whether the observed findings are relevant to them and are scientifically reliable. Such assessment clearly requires, as a minimum, a full description of the study's methods and transparent reporting of the findings.

For example, from a report of a nonrandomized study to compare two medical treatments, readers will expect to learn about the way in which the treatment was determined for individuals and which statistical analysis methods were employed to try to diminish the effect of confounding. Such key issues are addressed in reporting guidelines, in this case STROBE (Chapter 17).

In principle, other researchers ought to be able to repeat the study from the information given in the article (and perhaps also other referenced study publications). Readers should not have to be "research detectives" [5], yet often that is the reality. This fate applies especially to systematic reviewers who, having struggled to identify studies that are relevant to their review, have to struggle further to extract from publications essential information about study methods and detailed numerical results. It is common in reports of systematic reviews to see comments about the impossibility of extracting information. Box 1.1 in Chapter 1 shows some comments on the impact of reporting on the task of systematic reviewers. Reports that adhere fully to reporting guidelines greatly assist the systematic reviewer. Those that omit key information impede reviews and may lead to studies having to be excluded, which is wasteful and unacceptable [6].

Using reporting guidelines

Researchers

Planning a research study – writing the protocol

Reporting guidelines are primarily intended to aid the clear reporting of a study in a research paper. However, reporting guidelines are also useful when planning a study. Referring to reporting guidelines when writing the protocol will ensure that important details will not be forgotten and may suggest ways in which a study can be strengthened. For example,

certain study methods are especially critical to the validity and value of the research and it is therefore important that the protocol takes account of those elements. Taking reporting requirements into account will also help to structure a protocol method section in a way that can easily be transferred to a manuscript when writing the study up after its completion.

Some guidelines are accompanied by separate, detailed “explanation and elaboration” (E&E) documents, which provide extensive explanations of the rationale behind each checklist item and include illustrative examples of good reporting. These papers can be a particularly valuable resource at the planning stage. Not only do they explain methodological terms (e.g., CONSORT explaining allocation concealment in trials or STROBE describing effect modifiers in observational studies), but they also include examples of good reporting. A reporting guideline might thus provoke thoughts about possible improvements to the study design – for example, how to reduce the risk of bias or improve the reliability of the data being collected. However, E&E papers are neither a substitute for an adequate training in the conduct of such research studies nor for including a methodology expert in the project team.

An excellent example of the link between protocols and reporting guidelines is the SPIRIT guidance for preparing protocols of randomized trials (Chapter 7), which was developed in synergy with the CONSORT statement for reporting trial findings in journal articles (Chapter 9).

Documenting research findings in an article for journal publication

At the writing stage, reporting guidelines provide a useful reminder of fundamental details that should be addressed in the paper. As mentioned above, generic, methodology-focused guidelines such as CONSORT or STROBE suggest minimum sets of reporting requirements that should always be included when reporting this particular type of study. Other guidelines are more specific and recommend additional information that is important, for example, for a particular clinical area.

Researchers, as authors of reports describing their research, have primary responsibility for what is included in research reports. Although many research studies include experienced researchers among the authors, articles will often be drafted by less senior researchers who have little experience of writing articles for publication. Reporting guidelines may be especially valuable for such authors. Without good guidance, inexperienced authors frequently tend to copy the presentation style they see in published articles and thus perpetuate the bad reporting habits that are so prevalent.

The primary purpose of publishing research is to communicate findings to others. Indeed, authors should be aware of the moral responsibility to publish their findings honestly and transparently [7]. Two further general principles are relevant. First, authors should have in mind the possibility

that others will want to repeat what they have done, so the information in the article should be detailed enough to allow replication. Second, the study results should be presented in suitable detail to allow them to be included in a meta-analysis. These conditions will be far more likely to be met if authors are aware of, and follow, the relevant reporting guidelines.

Checklists indicate the information that ought to be reported. Although items appear in sequence in the checklist, there are various reasons why the order of presentation may vary from article to article. What matters is that the information is provided somewhere not precisely where it appears. To assist peer review, some journals ask authors to supply a completed checklist indicating the manuscript page on which each item appears. Much more helpfully, authors can also cut and paste key sections of the manuscript text into the boxes [8]. Some journals publish the completed checklist as a web appendix in the interest of transparency. They are most helpful to readers when populated by text rather than page numbers (especially if these refer to the submitted text rather than the published version). It is also possible to indicate in the main text the passages that address each of the checklist items, as is occasionally seen [9]. Even when a journal does not require authors to submit a completed reporting guideline checklist, these checklists are useful when finally checking the manuscript before submission.

Reporting guidelines indicate the *minimum* information that readers would expect to see in a journal article. However, it is a serious error to think that anything not in a checklist need not be mentioned. For example, it is important to document unexpected changes to study methods that occurred when a study was underway. Only CONSORT explicitly mentions reporting if the methods differed from what was planned in the protocol. Not all guidelines ask authors to report the amount of missing data, but this is usually important information. Likewise, it is sensible to report that a study was registered and ethical approval was obtained even if these items are not included in the relevant guidelines.

Some reporting guidelines recommend the inclusion of a diagram showing the flow of participants through the study. Flow diagrams provide a valuable overview of several key aspects of a study's conduct, with a clear statement of critical information about the numbers of participants. The CONSORT flow diagram [10] has been especially widely adopted, and examples are often seen, which imaginatively enhance the basic template with various types of additional information, or extend it to complex study designs. Unfortunately, many published flow diagrams do not adhere fully to the recommended structure, so that important information is missing [11].

Researchers should try to ensure that their article accurately describes the study as done and includes all important information. Readers expect that a study adhered to the prespecified plan except where otherwise indicated, the report should not misrepresent the study. Authors should, therefore,

resist attempts by editors or peer reviewers to remove important elements of the study methodology or alter the analysis from what was intended to something suggested by the results. It may, however, sometimes be valuable to include additional analyses suggested by reviewers – it is helpful then to indicate that these additional analyses were not prespecified. As always, readers are best served by full and transparent reporting.

Journal editors

Journal editors can use reporting guidelines in several ways. Perhaps the most common is to include a statement in the journal's instructions for authors about the desirability or, indeed, requirement of manuscripts conforming to specific guidelines. Such statements are quite common, especially for CONSORT [12, 13]. There is evidence that randomized controlled trials reporting is better in journals that have endorsed CONSORT in this way, but the impact is rather modest [14]. That may well be because the language used in journal instructions is often ambiguous or soft [12, 15], and also because there is often no effort to check whether authors have actually followed the guidelines. As a minimum, journals should consider the wording of statements about reporting guidelines in their instruction to authors, preferably strengthening the message about the importance of adherence. The EQUATOR Network (www.equator-network.org) has developed guidance for editors suggesting ways in which their journal can support better reporting of health research.

As noted above, some journals require authors to submit a completed checklist with their submission. As a minimum, that requirement ensures exposure of researchers to the specific reporting guidelines relevant to their study. Some journals use the checklists “in house” (i.e., as part of technical editing) to ensure that submitted manuscripts adhere to the guidelines, often focusing on a subset of the most important methodological issues. While all elements on a checklist are deemed important by their developers, clearly some are especially vital to assess scientific reliability, so it is sensible to focus on those elements in the first instance.

Journals could do much more to ensure that authors and peer reviewers give proper consideration to good reporting. Box 4.1 gives some suggestions for journals.

Peer reviewers

Medical journals ask peer reviewers to assess submitted manuscripts both to assess their suitability for publication and also to suggest ways in which, if published, the article might be improved. Clearly, peer review is a prime opportunity to ensure that published articles include key information about study methods and essential aspects of findings. Despite the high status given to peer review and its ubiquitous use by medical journals, there is

surprisingly limited guidance, or even consensus, on exactly what peer reviewers should do [16].

Reporting guidelines are a valuable aid to peer review, providing a reminder to reviewers of key issues that should be addressed in a submitted manuscript. Reviewers may well wish to first consider crucial aspects of methodology, as failure to address these key issues can render review of the remaining manuscript unnecessary. As noted above, some journals ask authors to supply a completed checklist indicating the manuscript page on which each item is addressed; if it is forwarded to the peer reviewers it can aid their task.

The persistent finding of numerous evaluations of published studies of various designs is that reporting of even the most important elements of study methods is poor – for example, fewer than half of the randomized trials give details about the method of randomization [14]. While the faults of the medical literature cannot be laid solely at the door of peer reviewers, it is clear that, currently, peer review is a badly missed opportunity to ensure that manuscripts provide readers with essential information about research studies.

Research funders

In addition to benefiting from the use of reporting guidelines by researchers whose studies they support, research funders are in a unique position to reinforce the requirements for accurate, complete, and transparent reporting. Funders hold one of the biggest incentives for scientists – funds for their future work. Some funders now have statements on their websites supporting the above-described reporting principles as part of their research integrity policies but hardly any of them request adherence to reporting guidelines, despite the fact that this is one of the cheapest and simplest ways to ensure better reporting quality of new research findings. Notable exceptions are the UK Medical Research Council and UK NIHR research program.

Whose responsibility is good reporting of research?

The widespread poor reporting of medical research represents a system failure, in which no one group has primary responsibility. Rather, there is clearly a collective failure across many key groups to appreciate the importance of adequate reporting of research. Why this should be so remains unclear; it is rather remarkable that so many individuals and organizations have persistently failed in this respect over decades.

Changes in behavior by several groups, notably researchers, editors, and peer reviewers, could lead to a rapid, major improvement in the usability

of research findings, and a consequent reduction in the waste currently observed [3, 6]. Inertia and the lack of incentives are barriers that must be overcome to maximize the benefit of current research for future patients.

Box 4.1: Recommendations for journal editors

How to support accurate and transparent reporting of health research studies and improve the reporting quality of submitted manuscripts:*

- (a) Incorporate an explicit philosophy of transparent, complete and accurate reporting and the use of reporting guidelines into your editorial policy.
- (b) Explore the available reporting guidelines on the EQUATOR website (www.equator-network.org); select well-developed guidelines appropriate for the reporting of research studies published in your journal.
- (c) Refer to selected guidelines in your 'Instructions to Authors,' ask or instruct authors to adhere to these guidelines, and motivate their use.
- (d) Consider including a link to the EQUATOR website as the portal for up to date reporting guidelines and other related resources. This will ensure that your links to instructions are current without additional effort for your journal.
- (e) Publish editorials to widen awareness of the importance of good reporting and the use of reporting guidelines by authors and peer reviewers, and indicate that your editorial policies will be incorporating them.
- (f) Consider strategies and actions to ensure (and verify) that authors realise and assume full responsibility for the reporting quality of their studies and adhere to reporting guidelines.

How to improve the peer review of submitted manuscripts:**

- (a) Increase transparency of your peer review process by providing your instructions to peer reviewers openly on your website. Ideally instructions should be collated in one place, made available as a printable pdf and include the date of their last revision. Consider linking to these from your instructions to authors to give your authors an indication of how their manuscript will be evaluated.
- (b) Alert your peer reviewers to the importance of good reporting and the availability of reporting guidelines which can act as an *aide memoire* for items indicating complete reporting. Provide or link to relevant guidelines/checklists and ask peer reviewers to use them during their manuscript assessment. This will make the review more helpful for authors in revising their manuscripts.
- (c) If you provide training for peer reviewers consider a module on reporting guidelines and how they can be used in manuscript assessment. Link to other available resources [17, 18].
- (d) Where provided, journals should link to resources for peer reviewers provided by their publishers.

Slightly modified from *[3] and **[16].

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